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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/481,990	Applicant(s) LESAGE ET AL.
	Examiner Robert Landsman	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 June 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 and 14-26 is/are pending in the application.

4a) Of the above claim(s) 1-10 and 14-26 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11 and 12 is/are rejected.

7) Claim(s) 11 and 12 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 11 January 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) Interview Summary (PTO-413) Paper No(s). _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/3/02 has been entered.

1. Formal Matters

- A. The Notice of Appeal, filed 4/3/02, has been entered into the record.
- B. In Preliminary Amendment A, filed 1/11/00, Applicants requested that claims 49-53 and 58-67 be deleted and that new claims 68-79 be added. However, there are only 14 claims (claims 1-14) in this application. Therefore, no claims were deleted and new claims 68-79 were renumbered under Rule 37 CFR 1.126 as new claims 15-26. In Paper No. 4, claims 1-26 were subject to restriction and Applicants elected Group II, claims 11-13, with traverse. This traversal was answered in the Office Action of Paper No. 6, dated 3/20/01. In Amendment B, (Paper No. 7) filed 6/22/01, Applicants cancelled claim 13 and requested a reconsideration of the restriction requirement. This traversal was answered, and maintained as FINAL, in the Final Office Action of Paper No. 11, dated 9/24/01. Therefore, claims 1-12 and 14-26 are pending in this application. Claims 1-10 and 14-26 have been withdrawn since they are drawn to a non-elected invention. Therefore, claims 11 and 12 are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title recites "Family of mammalian potassium channels, their cloning and their use, especially for the screening of drugs." However, the claims are drawn only to isolated and purified potassium channel proteins.

The following title is suggested: Isolated TWIK-1 potassium channel proteins.

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B. The specification is objected to since the first line of the specification does not recite that the present application claims benefit of parent application 08/749,816.

C. The instant specification does not comply with 37 CFR 1.77, which requires that the Abstract of the Disclosure contains a section header in upper case letters without underlining or bold type.

3. Claim Objections

A. The syntax of claim 11 could be improved by inserting the word "an" before "isolated." Claim 12 is objected to since it depends from claim 11.

4. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 11 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-13 of copending Application No. 09/436,265. Although the conflicting claims are not identical, they are not patentably distinct from each other because, even though the present claims are drawn to a TWIK-1 protein, or functional derivative thereof, the claims of both applications recite potassium channel proteins with 2 pore domains and 4 transmembrane domains. Since these are the only structural and functional limitations of the potassium channel of claim 11 of the present invention and since claim 12 of the present invention recites "functionally equivalent derivative," wherein no functional limitation has been recited in the claim, the claims of copending application fall under the broader claims of the present application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11 and 12 are directed to an invention not patentably distinct from claims 5-13 of commonly assigned application 09/436,265. The U.S. Patent and Trademark Office normally will not

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institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned application 09/436,265, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

B. The Examiner brings to Applicants' attention that claims 11-12 may be provisionally rejected under the judicially created doctrine of double patenting over claims 9-15 of copending Application No. 09/939,483. Upon performing a search of the inventors of the present application, Application No. 09/939,483 was identified as being drawn to potassium channel proteins with greater than 1 pore domain and 3 or more transmembrane domains. This meets the limitations of the potassium channel protein of the present invention which has 2 pore domains and 4 transmembrane domains. These are the only structural and functional limitations of the potassium channel of claim 11 of the present invention and claim 12 of the present invention recites "functionally equivalent derivative," wherein no functional limitation has been recited in the claim. However, the claims of Application No. 09/939,483 are drawn to numerous distinct groups and, at the time of this Office Action, Applicants have not been issued a Restriction under 35 USC 121. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

Claims 11 and 12 are directed to an invention not patentably distinct from claims 9-15 of commonly assigned 09/939,483. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/939,483, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this

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application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

C. The Examiner brings to Applicants' attention that claims 11-12 may be provisionally rejected under the judicially created doctrine of double patenting over claims 9-15 of copending Application No. 09/939,484. Upon performing a search of the inventors of the present application, Application No. 09/939,484 was identified as being drawn to potassium channel proteins with greater than 1 pore domain and 3 or more transmembrane domains. This meets the limitations of the potassium channel protein of the present invention which has 2 pore domains and 4 transmembrane domains. These are the only structural and functional limitations of the potassium channel of claim 11 of the present invention and claim 12 of the present invention recites "functionally equivalent derivative," wherein no functional limitation has been recited in the claim. However, the claims of Application No. 09/939,484 are drawn to numerous distinct groups and, at the time of this Office Action, Applicants have not been issued a Restriction under 35 USC 121. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

Claims 11 and 12 are directed to an invention not patentably distinct from claims 9-15 of commonly assigned application 09/939,484. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/939,484, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting

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subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

D. The Examiner brings to Applicants' attention that claims 11-12 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 09/892,360. Upon performing a search of the inventors of the present application, Application No. 09/892,360 was identified as being drawn to potassium channel proteins. However, Application No. 09/892,360 was not available to the Examiner at the time of this Office Action. Therefore, Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

Claims 11 and 12 are directed to an invention which may not be patentably distinct from one or more claims of commonly assigned 09/892,360. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/892,360, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

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5. Claim Rejections - 35 USC § 101

A. Claims 11 and 12 remain rejected under 35 USC 101 for the reasons already of record on pages 3-7 of the Final Office Action dated 9/24/01 as well as on the Advisory Action dated 3/5/02. Applicants argue that the claimed invention has utility for the reasons already argued in the Response of 12/14/01. These arguments have been addressed in the Advisory Action dated 3/5/02. Applicants further argue in the present Response that pages 14 and 15 of the specification make it clear that cells expressing TWIK-1 potassium channels, or channels exhibiting the properties and structure of TWIK-1 channel type are useful for the screening of substances capable of modulating activity of the TWIK-1 potassium channels and to identify drugs useful in the treatment of heart and nervous system diseases such as epilepsy, arrhythmias and vascular disease. Applicants also argue that nucleic acid molecules encoding TWIK-1 can be used to produce transgenic animals for use in studying TWIK-1-related diseases. Applicants further provide references which discuss the benefits of potassium channels and teach that a number of different diseases are related to malfunctions of potassium channels. They also argue that TWIK-1 is widely expressed in human tissue and is modulated by PKC, hormones and neurotransmitters and can be used to develop new therapeutics to treat psychiatric and neurological disorders.

These arguments have been considered, but are not deemed persuasive. First, though potassium channels have been shown to be involved in a wide variety of disorders, including those of the heart and nervous system, and though Applicants have demonstrated that the TWIK-1 potassium channels of the present invention are, in fact, potassium channels, Applicants have not demonstrated what the utility of these proteins would be in the treatment of any of these diseases. It is not known what one of ordinary skill in the art would do with the knowledge that the protein of the present invention is a TWIK-1 protein. The production of transgenic animal to study diseases is a future use to try to identify the utility of the present invention. Applicants have only speculated that the TWIK-1 protein of the present invention is generally involved with the cardiac and neurological diseases argued in the response, including mood disorders, schizophrenia, epilepsy and memory disorders. Mood and memory disorders alone are very general categories and can include such diseases as depression, anxiety, Alzheimer's, short-term memory loss, etc. and Applicants have not demonstrated the utility of the TWIK-1 proteins of the invention in any of these diseases, only that it is believed that these proteins are involved in these diseases. The fact that TASK and TREK proteins have been shown to be involved with inhalation anesthetics does not confer a utility to the TWIK-1 proteins of the present invention because TWIK-1 represents a novel family of receptors (last paragraph on page 2 of the specification).

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6. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 11 and 12 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 7 of the Office Action dated 9/24/01, as well as for the reasons given in the above rejection under 35 USC 101. This rejection, though not withdrawn, was not addressed in the Advisory Action of Paper No. 13, filed 3/5/02. Regardless, the rejection of claims 11 and 12 under 35 USC 112, first paragraph, is being restated in this Office Action.

B. Furthermore, even if claims 11 and 12 were shown to possess utility under 35 USC 101, they would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while then being enabling for the isolated TWIK protein of SEQ ID NO:2, would not reasonably provide enablement for any and all TWIK proteins having two pore domains and four transmembrane domains, or “functionally equivalent derivatives” of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming any and all TWIK proteins having “two pore domains and four transmembrane domains,” or “functionally equivalent derivatives” of SEQ ID NO:2. These proteins would have one or more amino acid substitutions, deletions, insertions and/or additions to SEQ ID NO:2. Applicants disclose that the protein of SEQ ID NO:2 is the first member of a new structural and functional group of potassium channels and, therefore, the specification only provides guidance and working examples of one TWIK potassium channel protein (SEQ ID NO:2). The characteristics of this protein are disclosed in the paragraph bridging pages 2 and 3 of the specification. The only disclosed characteristics of these TWIK proteins are that they have two “P” domains, four transmembrane segments and exhibit weak inward rectification properties. It would appear to the artisan that residues in the P and transmembrane domains would be required in an attempt to maintain the structural and functional characteristics of these proteins. However, Applicants have not taught which amino acid residues in these domains must be maintained in order to maintain said characteristics and which can be altered, nor have Applicants taught what critical amino acids outside of

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these domains would also be required to maintain said characteristics, since these proteins comprise more than just P and transmembrane domains. Simply maintaining the P and transmembrane domains allows for the remainder of the protein of SEQ ID NO:2 to be either substituted, deleted, or in some way altered and Applicants have not enabled one of ordinary skill in the art to make a functional TWIK protein which has only the claimed domains. Furthermore, it is not *predictable* to one of ordinary skill in the art how to make a functional TWIK potassium channel protein other than that of SEQ ID NO:2, or how to make any functionally equivalent derivatives of SEQ ID NO:2 since the only known requirements for protein function are the pore and transmembrane domains and the artisan would not be able to predict what other residues are critical to maintain the structural and functional characteristics of the protein.

In summary, the breadth of the claims is excessive with regard to Applicants claiming any and all TWIK proteins having “two pore domains and four transmembrane domains,” or “functionally equivalent derivatives” of SEQ ID NO:2. Applicants only provide guidance and working examples of one TWIK potassium channel protein (SEQ ID NO:2) and have not taught which amino acids, including those in the P and transmembrane domains, must be maintain in order to maintain the structural and functional characteristics of these proteins. Furthermore, it is not predictable to one of ordinary skill in the art how to make a functional TWIK potassium channel protein other than that of SEQ ID NO:2, or how to make any functionally equivalent derivatives of SEQ ID NO:2 since the only known requirements for protein function are the pore and transmembrane domains and the artisan would not be able to predict whiat other residues are critical to maintain the structural and functional characteristics of the protein. Therefore, the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. TWIK proteins having “two pore domains and four transmembrane domains,” or “functionally equivalent derivatives” of SEQ ID NO:2. These proteins would have one or more amino acid substitutions, deletions, insertions and/or additions to SEQ ID NO:2. The specification and claims indicate only these minimal distinguishing attributes which are shared by the members of the genus of TWIK proteins. Thus the scope of the claims includes numerous structural variants, and the

genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are only minimally disclosed and only a small number of common structural attributes identify the members of the genus (i.e. 2 pore domains and 4 transmembrane domains). The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:2 alone is insufficient to describe the genus.

The specification provides a written description of only one of these protein constructs (SEQ ID NO:2). No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical amino acid residues which would structurally characterize the genus of TWIK proteins claimed, because it is unknown and only minimally described what structurally constitutes any different TWIK proteins, including those from any different species, which are further not described, or any different proteins which are "functionally equivalent derivatives" of SEQ ID NO:2; thereby not meeting the written description requirement under 35 USC 112, first paragraph. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

8. Conclusion

- A. No claim is allowable.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.

Patent Examiner

Group 1600

August 26, 2002

